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Abbreviated 510 (K) SUMMARY

As Required by the Safe Medical Devices Act of 1990

Apex Dental Materials, Inc.
23329 Mallard Court
Deer Park, IL 60010
Phone: (877) 273-9123

Abbreviated 510 (K) Submission Date: July 12th, 2006

Contact Person: Chris Kulton

Device Name:
Trade Name: SURPASS™
Common Name: Dental Bonding Adhesive
Classification Name: Resin Tooth Bonding Agent, per 21 CFR parts 872.3200

Classification:
Regulatory Class: II
Product Code: KLE

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE

ECLIPTOMER (510K number K945604, Bisco, Inc.) is a universal dental adhesive system that is designed to bond composite to dentin, enamel, cast metals, treated porcelain and set amalgam. This system is also designed for indirect techniques as well as amalgam bonding.

ECLIPTOMER (510K number K945604, Bisco, Inc.) is an acetone-based primer that is dependent on a clean etched dentin/enamel surface that is visibly moist. Its physical properties are similar to the applicant device and uses are identical. Like the applicant device, ECLIPTOMER (510K number K945604, Bisco, Inc.) is one component used in conjunction with

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a complete dental bonding system. It hardens by a light cure polymerization mechanism employing a photo initiator, and a chemical activator.

Summary continued:

DESCRIPTION OF APPLICATION DEVICE

SURPASS™ is a light cured (free radical polymerization), self-etching dental adhesive system, designed to provide a dentist with an increased ease of use that is less technique sensitive. The bonding system combines both the etchant and primer applications into one simple step followed by a thin layer of unfilled bonding resin. Thus, allowing for more predictable clinical results without sacrificing bond strength integrity.

SURPASS™ 2 is an ethanol-based adhesive that is dependent on the prepared surface of its conditioner (SURPASS™ 1). This acidic conditioner application is a procedure that is very similar to the phosphoric acid etching process of dentin/enamel substrate in the ECLIPTOMER (510K number K945604, Bisco, Inc.) system. Applying the SURPASS™ 2 (adhesive resin) directly to the conditioner prepared surface, assures proper moistness on the bonding interface, resulting in a reliable simplified bonding protocol. Once SURPASS™ 2 has been dried a thin layer of SURPASS™ 3 is applied to the SURPASS™ 2 surface and light cured for 20 seconds. The SURPASS™ 3 acts as a superior tie layer between SURPASS™2 and the filling material of choice.

Summary continued:

INTENDED USES OF APPLICANT DEVICE

SURPASS™ is a universal adhesive system that when properly employed, can be used to seal enamel/dentin prior to restoring with light-cured or self-cured composite materials. Also, in situations of indirect restorations, the bonding system can be used to seal a preparation when using a light-cured, self-cured or dual-cured composite cement or glass ionomer or resin-modified glass ionomer cement. In addition, the system allows the dentist to bond a post and core, along with the use to treat hypersensitive and/or exposed root surfaces.

PERFORMANCE CHARACTERISTICS and CONCEPTS

SURPASS™ has similar handling to the ECLIPTOMER (510K number K945604, Bisco, Inc.) adhesive system. From the physical testing observations and analysis, including shear bond strength to dentin and enamel, we suggest that SURPASS™ is substantially equivalent to ECLIPTOMER (510K number K945604, Bisco, Inc.). Along with this we would suggest the individual components of SURPASS™ are long-time industry standards and are utilized in numerous dental bonding systems currently marketed in the United States (see Confidential Formulation Details on page 5). In addition, SURPASS™ is essentially our Simplicity® Adhesive System (510K: K020570) with an added bonding resin (SURPASS™ 3). SURPASS™ has the same indication for use and same base composition as the Simplicity® Adhesive System (510K: K020570).

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Indications for Use

510(K) Number (if known):

Device name: SURPASS™

Indications For Use:

- Restorations: to seal enamel/dentin prior to restoring with light-cured or self-cured composite materials.
- Indirect Restorations: to seal a preparation when using a light-cured, self-cured or dual-cured composite cement or glass ionomer or resin-modified glass ionomer cement.
- Desensitization: to treat hypersensitive and/or exposed root surfaces.
- To bond in a post and core

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRL, Office of Device Evaluation (ODE)

Prescription use X (Per 21 CFR 801.109) OR Over- The- Counter Use

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2006

Mr. Chris Kulton
Apex Dental Materials, Incorporated
23329 Mallard Court
Deer Park, Illinois 60010

Re: K061981
Trade/Device Name: Surpass™
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: July 12, 2006
Received: July 17, 2006

Dear Mr. Kulton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061981

Indications for Use

510(K) Number (if known):

Device name: SURPASS™

Indications For Use:

- Restorations: to seal enamel/dentin prior to restoring with light-cured or self-cured composite materials.
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Concurrence of CDRL, Office of Device Evaluation (ODE)

Prescription use X
(Per 21 CFR 801.109

OR

Over- The- Counter Use

(Optional Format 1-2-96)

Abbrevaited 510K Submission for SURPASS™
Apex Dental Materials,
23329 Mallard Court
Deer Park, IL 60010

...on Sign-Off)
...n of Anesthesiology, General Hospital,
...tion Control, Dental Devices
...Number K061981